DETAILED ACTION

This action is in response to applicant's pre-appeal brief request received 10 December 2007. Claims 19-29 remain withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
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> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7, and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frayne et al. (Patent No. 6,361,759 B1).

Regarding claim 1, Frayne et al. disclose an implantable medical device (column 5, line 2) comprising a support structure (stent; column 5, line 2) formed such that magnetic field changes proximate the support structure are substantially unobstructed (for example, see column 4, lines 60-64). The coating is considered to be part of the support structure. Therefore, Frayne discloses a magnetic material at least embedded into at least part of the support structure. In the alternative, it would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to embed the magnetic material into at least part of the support structure, since the applicant discloses the magnetic material may be coated on the support structure and has not disclosed that embedding the magnetic material into at least part of the support structure solves any stated problem or is used for any particular

purpose and it appears that the invention would perform equally well with a magnetic coating. Furthermore, embedding magnetic materials into at least a portion of a support structure is well known in the art.

Regarding claim 7, the magnetic material disclosed is paramagnetic (column 4, lines 60-61).

Regarding claim 9, the magnetic material includes at least one of the materials claimed (e.g. gadolinium; column 6, lines 6-12).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1-3, 5-6, 10-12, 14, 16-18, 34, 36, and 38-40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhong et al. (Publication No. 2003/0100830 A1).

Regarding claims 1, 2, 12, and 34, Zhong et al. disclose an implantable medical device (for example, see paragraph 22) comprising a support structure formed such that magnetic field changes proximate the support structure is substantially unobstructed (for example, see paragraphs 13 and 20). It is inherent that the device disclosed forms a generally tubular structure since endovascular stents (for example, see paragraph 68) are generally tubular. Furthermore, Zhong et al. inherently disclose the implantable

device may be made of a substantially non-magnetic material (e.g., superelastic shape memory alloys; paragraph 68), since it is disclosed that implantable devices are composed of materials that do not produce adequate signals for detection by MRI techniques (for example, see paragraph 8). The coating is considered to be part of the support structure. Therefore, Zhong discloses a magnetic material at least embedded into at least part of the support structure. In the alternative, it would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to embed the magnetic material into at least part of the support structure, since the applicant discloses the magnetic material may be coated on the support structure and has not disclosed that embedding the magnetic material into at least part of the support structure solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with a magnetic coating. Furthermore, embedding magnetic materials into at least a portion of a support structure is well known in the art.

Regarding claims 3, 5, and 6, the tubular structure disclosed may be made of a metals, metal alloys, polymeric materials, ceramics, composites of any such materials, and biodegradable materials (paragraph 68).

Regarding claims 14, 16, 36, and 38 the material disclosed is paramagnetic (paragraph 20), and it is at least one of the materials claimed (e.g., gadolinium; paragraph 20).

Zhong et al. disclose that in addition to covering the entire tubular structure, the magnetic coating may also be provided only on selected portions (paragraph 52) of the

tubular structure. Therefore, it is inherent that the magnetic material may be applied only to at least one end portion or only to the first end portion and the second end portion. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the magnetic material only to at least one end portion, only to the first end portion and the second end portion, or to any other selected portion thereof in order to enhance the visibility or to render such portions visible under MRI (paragraph 52).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 8, 15, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al.

Zhong et al. disclose that ferromagnetic material is well known in the art for making devices visible under MRI. Applicant has not disclosed that a ferromagnetic

material provides an advantage over paramagnetic material, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with ferromagnetic material because the function of the magnetic material is to render the device visible under MRI and it is well known in the art that ferromagnetic particles are useful for this purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the magnetic material of Zhong et al. to obtain the invention as claimed in claims 8, 15, and 37.

8. Claims 4, 13, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. in view of Klumb et al. (Patent No. 6,921,414 B2).

Zhong et al. disclose the device as described above, however, Zhong et al. do not disclose the specific metallic material claimed. Klumb et al. disclose a generally tubular structure (Figure 3, element 122) and unlike Zhong et al., Klumb et al. teach the device is made of at least one of the metallic materials claimed (e.g., Nitinol; column 1, line 52) so that the device can radially expand when it is deployed at the target site (lines 50-67). Therefore, to construct the device of Zhong et al. of Nitinol as taught by Klumb et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a device with self-expanding properties.

9. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klumb et al. in view of Zhong et al.

Regarding claim 30, Klumb et al. disclose a support structure (Figure 7A, element 12) including a segment (the whole support structure) helically oriented about

an axis of an elongated medical instrument (catheter 136). Klumb et al. do not disclose the material is at least one of those claimed and that magnetic material is at least embedded into the segment. Zhong et al. discloses a support structure formed such that magnetic field changes proximate the support structure is substantially unobstructed (for example, see paragraphs 13 and 20). Zhong teaches the material of the support structure is at least one of those claimed (e.g., ceramic; paragraph 68) and that magnetic material is at least embedded into the segment, since the coating is considered part of the support structure, in order to render the device visible under MRI (for example, see paragraph 1). In the alternative, it would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to embed the magnetic material into at least part of the support structure, since the applicant discloses the magnetic material may be coated on the support structure and has not disclosed that embedding the magnetic material into at least part of the support structure solves any stated problem or is used for any particular purpose and it appears that the invention would perform equally well with a magnetic coating. Furthermore, embedding magnetic materials into at least a portion of a support structure is well known in the art. Therefore, to construct the device of Klumb et al. as taught by Zhong et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to view the device under MRI during and/or after insertion.

Regarding claims 31 and 33, the material disclosed is paramagnetic (paragraph 20), and it is at least one of the materials claimed (e.g., gadolinium; paragraph 20).

Regarding claim 32, Klumb et al. in view of Zhong et al. disclose that ferromagnetic material is well known in the art for making devices visible under MRI. Applicant has not disclosed that a ferromagnetic material provides an advantage over paramagnetic material, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with ferromagnetic material because the function of the magnetic material is to render the device visible under MRI and it is well known in the art that ferromagnetic particles are useful for this purpose. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the magnetic material of Klumb et al. in view of Zhong et al. to obtain the invention as claimed in claim 32.

Response to Arguments

10. Applicant's arguments filed 07 December 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art utilized do not disclose or suggest all the limitations claimed. Examiner respectfully disagrees.

Applicant argues that Frayne does not disclose or suggest a magnetic material at least **embedded** into at least part of the support structure as required by the amended claims. However, the magnetic coating is considered part of the support structure. Therefore, the magnetic material is at least embedded into at least part of the support structure as claimed. In the alternative, such a modification is well known in the art and would have been obvious to one having ordinary skill in the art (see new rejection above for details).

Applicant argues that Zhong does not teach or suggest **embedding** the magnetic material into the substrate as required by the amended claims. However, the magnetic coating is considered part of the support structure. Therefore, the magnetic material is at least embedded into at least part of the support structure as claimed. In the alternative, such a modification is well known in the art and would have been obvious to one having ordinary skill in the art (see new rejection above for details).

Conclusion

Applicant's amendment dated 30 March 2007 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-

9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
April 3, 2008

/(Jackie) Tan-Uyen T. Ho/
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